2018 Current Fiscal Year Report: Tobacco Products Scientific Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Tobacco Products Scientific Advisory Committee	70466

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	08/12/2009		

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
H.R. 1256 Family Smoking Prevention and Tobacco Control Act; FD&C 21 U.S.C. 387q	06/22/2009	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$19,257.00	$48,122.00
18a(2). Personnel Pmts to Federal Members	$0.00	$4,375.00
18a(3). Personnel Pmts to Federal Staff	$292,710.00	$298,961.00
18a(4). Personnel Pmts to Non-Member Consultants	$5,238.00	$17,499.00
18b(1). Travel and Per Diem to Non-Federal Members	$14,102.00	$28,338.00
18b(2). Travel and Per Diem to Federal Members	$696.00	$2,792.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$3,325.00	$4,107.00

18c. Other(rents,user charges, graphics, printing, mail, etc.)	$116,478.00	$162,221.00
18d. Total	$451,806.00	$566,415.00
19. Federal Staff Support Years (FTE)	1.65	1.65

20a. How does the Committee accomplish its purpose?

The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. One voting member is an officer or employee of a state or local government or of the Federal Government. One voting member is a representative of the general public. In addition to the voting members, the Committee includes 3 non-voting members who are identified with industry interests. These members include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. This final position can be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Committee.

20c. How frequent and relevant are the Committee Meetings?

This committee held two meeting in FY18. One to discuss modified risk tobacco product applications (MRTPAs), submitted by Philip Morris Products S.A. for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks, and one to discussed modified risk tobacco product applications (MRTPAs), submitted by R.J. Reynolds Tobacco Company for six products: MR0000068: Camel Snus Frost, MR0000069: Camel Snus Frost Large, MR0000070: Camel Snus Mellow, MR0000071: Camel Snus Mint, MR0000072: Camel Snus Robust, and MR0000073: Camel Snus Winterchil.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research, and/or clinical practice. Their advice and input lends credibility to regulatory decisions made and helps those decisions stand up to intense public scrutiny. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at great expense to the government.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

No reports were required of the committee in this fiscal year. The FD&C Act provides for mandatory referral of modified risk tobacco product applications (MRTPA) to the Committee under section 911(f)(1). 21 U.S.C. 387k (f)(1). As such, the committee reviewed MRTP applications submitted by Philip Morris Products S.A. on January 24-25, 2018 and MRTP applications submitted by R.J. Reynolds Tobacco Company on September 13-14, 2018.

Designated Federal Officer

Caryn Cohen Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Bailey, William	02/01/2017	01/31/2021	University of Kentucky Research and Education Center	Representative Member
Bassett, Mary	02/16/2018	08/31/2018	New York City Dept. of Health and Mental Hygiene	Special Government Employee (SGE) Member
Bierut, Laura	02/01/2017	01/31/2021	Professor of Psychology and Co-director, Department of Psychiatry, Washington Unversity School of Medicine	Special Government Employee (SGE) Member
Duffy, Sonia	02/16/2018	01/31/2022	Dept. of Veterans Affairs	Regular Government Employee (RGE) Member
Fagan, Pebbles	03/03/2015	01/31/2018	Associate Professor, Cancer Prevention and Control Program, University of Hawaii	Special Government Employee (SGE) Member
Giovino, Gary	03/03/2015	01/31/2019	Professor and Chair, Department of Community Health and Health Behavior, The State University of New York at Buffalo	Special Government Employee (SGE) Member
Huang, Philip	04/13/2016	01/31/2018	Medical Director, Austin/Travis County Health and Human Services Department	Special Government Employee (SGE) Member
McKinney, Willie	12/07/2016	01/31/2020	Vice President, Regulatory Sciences, Altria Client Services, LLC	Representative Member
Mermelstein, Robin	04/13/2016	01/31/2020	University of Illinois at Chicago	Special Government Employee (SGE) Member
Ossip, Deborah	02/01/2017	01/31/2021	Professor, Department of Public Health Sciences, University of Rochester	Special Government Employee (SGE) Member
O'Connor, Richard	04/01/2014	01/31/2020	Associate Professor of Oncology, Department of Cancer Prevention and Population Sciences, Roswell Park Cancer Institute	Special Government Employee (SGE) Member
Thrasher, James	04/13/2016	01/31/2020	University of South Carolina	Special Government Employee (SGE) Member

Weitzman, Michael	02/01/2017 01/31/2021	Professor, Department of Pediatrics, New York University	Special Government Employee (SGE) Member

Number of Committee Members Listed: 13

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Tobacco Products Scientific Advisory Committee supports FDA's strategic priorities by reviewing and evaluating safety, dependence, and health issues relating to tobacco products and making appropriate recommendations to the Commissioner of Food and Drugs.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	

$500,001 - $1,000,000 ☐
$1,000,001 - $5,000,000 ☐
$5,000,001 - $10,000,000 ☐
Over $10,000,000 ☐
Cost Savings Other ☐

Cost Savings Comments
The utilization of the (insert committee) enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency and to obtain the services of these experts only on an as needed bases rather than on a full time basis. The service of the committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
8

Number of Recommendations Comments
The committee made 8 recommendations from FY10 through FY18 - See question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
0%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
0%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the

advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

The Agency will use the committee's advice in implementing the Family Smoking Prevention and Tobacco Control Act.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A